

AMENDMENTS TO THE CLAIMS

Please cancel claims 1-92 without prejudice and add claims 93-113, as shown below. This Listing of Claims will replace all prior versions and listings of claims in the above-referenced application.

LISTING OF CLAIMS

1-92. (Cancelled)

93. (New) A composition comprising a biologically active agent and a peptide 9 to 25 amino acids in length, wherein the peptide has at least 85% identity with 9 contiguous amino acids of the extracellular domain of SEQ ID NO: 900, and wherein the peptide reduces transepithelial resistance (TER) of an epithelial cell layer.

94. (New) The composition of claim 93, wherein the peptide comprises an amino acid sequence selected from the group consisting of GVNPTAQSS (SEQ ID NO: 33), GSLYGSQIY (SEQ ID NO: 34), AATGLYVDQ (SEQ ID NO: 32), ALCNQFYTP (SEQ ID NO: 35), and YLYHYCVVD (SEQ ID NO: 42).

95. (New) The composition of claim 93, wherein the peptide comprises GVNPTAQSS (SEQ ID NO: 33).

96. (New) The composition of claim 93, wherein the peptide comprises GSLYGSQIY (SEQ ID NO: 34).

97. (New) The composition of claim 93, wherein the peptide comprises AATGLYVDQ (SEQ ID NO: 32).

98. (New) The composition of claim 93, wherein the peptide comprises ALCNQFYTP (SEQ ID NO: 35).

99. (New) The composition of claim 93, wherein the peptide comprises YLYHYCVVD (SEQ ID NO: 42).

100. (New) The composition of claim 93, wherein the biologically active agent is selected from the group consisting of a small molecule drug, a peptide, a protein, monoclonal, polyclonal antibody, and a vaccine agent.

101. (New) The composition of claim 93, wherein the biologically active agent is selected from the group consisting of an opiod, opiod antagonist, corticosterone, anti-inflammatory, androgen, estrogen, progestin, muscle relaxant, vasodilator, antihistamine, histamine receptor site blocking agent, antitussive, antiepileptic, anti-fungal agent, antibacterial agent, cancer therapeutic agent, antioxidant, antiarrhythmic agents, and an antihypertensive agent.

102. (New) The composition of claim 93, wherein the biologically active agent is selected from the group consisting of an anti-sense oligonucleotide, and an RNA, DNA or viral vector comprising a gene encoding a therapeutic peptide or protein.

103. (New) The composition of claim 93, wherein said biologically active agent is a therapeutic protein or peptide selected from the group consisting of tissue plasminogen activator (TPA), epidermal growth factor (EGF), fibroblast growth factor (FGF), platelet derived growth factor (PDGF), transforming growth factor (TGF-alpha or beta), vasoactive intestinal peptide, tumor necrosis factor (TNF), hypothalamic releasing factors, prolactin, thyroid stimulating hormone (TSH), adrenocorticotrophic hormone (ACTH), parathyroid hormone (PTH), follicle stimulating hormone (FSH), luteinizing-hormone releasing hormone (LHRH), endorphins, glucagon, calcitonin, oxytocin, carbetocin, aldoetecone, enkaphalins, somatostin, somatotropin, somatomedin, gonadotrohin, estrogen, progesterone, testosterone, alpha-melanocyte stimulating hormone, non-naturally occurring opiods, lidocaine, ketoprofen, sufentainil, terbutaline, droperidol, scopolamine, gonadorelin, ciclopirox, olamine, buspirone, calcitonin, cromolyn sodium or midazolam, cyclosporin, lisinopril, captopril, delapril, cimetidine, ranitidine, famotidine, superoxide dismutase, asparaginase, arginase, arginine deaminase, adenosine deaminase ribonuclease, trypsin, chemotrypsin, papain, bombesin, substance P, vasopressin, alpha-globulins, transferrin, fibrinogen, beta-lipoproteins, beta-globulins, prothrombin, ceruloplasmin, alpha₂-glycoproteins, alpha₂-globulins, fetuin, alpha-lipoproteins, alpha-globulins, albumin, and prealbumin.

104. (New) The composition of claim 93, wherein the biologically active agent is selected from the group consisting of a therapeutic protein or peptide effective as a hematopoietic agent, cytokine agent, anti-infective agent, antidementia agent, antiviral agent, antitumoral agent, antipyretic agent, analgesic agent, anti-inflammatory agent, antiulcer agent, antiallergic agent, antidepressant agent, psychotropic agent, cardiotonic agent, antiarrhythmic agent, vasodilator agent, antihypertensive agent, antidiabetic agent, anticoagulant agent, cholesterol-lowering agent, hormone agent, anti-osteoporosis agent, antibiotic agent, and bacterial toxoid.

105. (New) The composition of claim 93, wherein the biologically active agent is a dopamine receptor agonist.

106. (New) The composition of claim 93, wherein the biologically active agent is apomorphine or a pharmaceutically acceptable salt or derivative thereof.

107. (New) The composition of claim 93, the composition further comprising one or more mucosal delivery-enhancing agents.

108. (New) The composition of claim 107, wherein the mucosal delivery-enhancing agent is selected from the group consisting of:

- (a) an aggregation inhibitory agent;
- (b) a charge modifying agent;
- (c) a pH control agent;
- (d) a degradative enzyme inhibitory agent;
- (e) a mucolytic or mucus clearing agent;
- (f) a ciliostatic agent;
- (g) a membrane penetration-enhancing agent selected from (i) a surfactant, (ii) a bile salt, (iii) a phospholipid additive, mixed micelle, liposome, or carrier, (iv) an alcohol, (v) an enamine, (vi) an NO donor compound, (vii) a long-chain amphipathic molecule (viii) a small hydrophobic penetration enhancer; (ix) sodium or a salicylic acid derivative; (x) a glycerol ester of acetoacetic acid (xi) a cyclodextrin or beta-cyclodextrin derivative, (xii) a medium-chain fatty acid, (xiii) a chelating agent, (xiv) an amino acid or salt thereof, (xv) an N-acetylamino acid or

salt thereof, (xvi) an enzyme degradative to a selected membrane component, (xvii) an inhibitor of fatty acid synthesis, or (xviii) an inhibitor of cholesterol synthesis; or (xix) any combination of the membrane penetration enhancing agents recited in (i)-(xix);

(h) a second modulatory agent of epithelial junction physiology;

(i) a vasodilator agent;

(j) a selective transport-enhancing agent; and

(k) a stabilizing delivery vehicle, carrier, support or complex-forming species

with which the biologically active agent is effectively combined, associated, contained, encapsulated or bound resulting in stabilization of the active agent for enhanced mucosal delivery, wherein the one or more mucosal delivery-enhancing agents comprises any one or any combination of two or more of the mucosal delivery-enhancing agents recited in (a)-(k), and wherein the formulation of the biologically active agent with the mucosal delivery-enhancing agents provide for increased bioavailability of the biologically active agent delivered to a mucosal surface of a mammalian subject.

109. (New) The composition of claim 107, wherein the mucosal delivery-enhancing agent is a cyclodextrin or beta-cyclodextrin derivative.

110. (New) The composition of claim 107, wherein the mucosal delivery-enhancing agent is a chelating agent.

111. (New) The composition of claim 107, wherein the mucosal delivery-enhancing agent is an alcohol.

112. (New) The composition of claim 107, wherein the mucosal delivery-enhancing agent is a long-chain amphipathic molecule.

113. (New) The composition of claim 107, wherein the mucosal delivery-enhancing agent is a medium-chain fatty acid.